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10/594,587	04/22/2008	Norihiro Yamaguchi	063140	5603
38834 7590 03/04/2009 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036				
EXAMINER MCKANE, ELIZABETH L.				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/594,587

**Applicant(s)**

YAMAGUCHI ET AL.

**Examiner**

ELIZABETH L. MCKANE

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/55/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sudou et al. (JP 2002-303618).

Sudou et al. teaches an ink composition for detecting an oxidizing gas (hydrogen peroxide plasma) containing a dye such as a triarylmethane dye (sulfophthalane) and an anthraquinone dye (triarylmethane). See paragraph [0007]. The composition of Sudou et al. further includes a binder (paragraph [0021]) and a color or paint which does not change color in an oxidizing gas atmosphere (paragraph [0025]). The composition is applied as a layer to a wrapping material. See paragraph [0008].

3. Claims 9, 12-17, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Omatsu et al. (US 2001/0054374).

Omatsu et al. teaches an ink composition for detecting hydrogen peroxide plasma sterilization (Abstract). The composition includes an anthraquinone dye (paragraph [0019]), a nitrogen-containing (amide) polymer (paragraph [0028]), and a cationic surfactant (paragraph [0024]). The cationic surfactant can be alkyltrimethylammonium salt (paragraph [0026]) and the composition may further include a cellulose resin binder and a silica extender. See Example 1. The nitrogen-containing polymer (amide) may be used as a binder in an amount of 5-35 wt.%. See

paragraph [0031]. Omatsu et al. further discloses that the ink composition may include a coloring material which does not change color in the plasma sterilization atmosphere (paragraph [0023]). In use, Omatsu et al. teaches that the ink composition is applied as a layer to a support and may further include a non-color changing layer. See paragraphs [0034]-[0037].

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sudou et al..

Sudou et al. discloses that the sterilization indicators may use a combination of two or more dyes to achieve the desired hue in the indicator (paragraph [0020]). Since Sudou et al. also teaches the use of both a triarylmethane dye (sulfophalane) and an anthraquinone dye (triarylmethane), it would have been obvious to one of ordinary skill in the art to combine the use of an anthraquinone dye with the triarylmethane dye in order to realize the desired color attributes of the indicator.

8. Claims 2, 3, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sudou et al. as applied to claims 1 and 7 above, and further in view of Omatsu et al..

With respect to claims 2 and 3, Sudou et al. is silent with respect to use of a cationic surfactant. Omatsu et al., however, discloses use of a cationic surfactant such as an alkyltrimethylammonium salt in an indicator containing an anthraquinone dye in order to obtain improved detection sensitivity when using an anthraquinone dye. See paragraph [0025]. For this reason, it would have been obvious to employ a cationic dye in the composition of Sudou et al..

As to claim 8, although Sudou et al. fails to teach a non-color changing layer, this is evidenced by Omatsu et al.. In fact, Omatsu et al. discloses that a non-color

changing layer can assist in determining the end-point of the plasma sterilization process (paragraphs [0037]-[0045]). Thus, one would have found it obvious to add a non-color changing layer to the indicator of Sudou et al..

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al..

Although Omatsu et al. is silent with respect to cracks specifically in the layer, it is known and obvious in the art that 'cracks' often appear when printing dyes to substrates, forming as the ink dries.

10. Claims 10, 11, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al. as applied to claim 9 above, and further in view of Sudou et al..

With respect to claims 10 and 11, Omatsu et al. teaches use of an amide resin, but is silent to a polyamide resin. Sudou et al. discloses the known use of a polyamide resin in an indicator composition. See paragraph [0017]. It would have been obvious to one of ordinary skill in the art to use an amide known in the art as being an effective resin in indicator dye compositions. As to the particular polyamide, it is deemed obvious to one of ordinary skill in the art to choose an appropriate and known polyamide, especially where the results are not unexpected.

As to claim 20, Omatsu et al. fails to disclose an organic amine. Sudou et al. teaches that an organic amine can be used as a discoloration auxiliary agent. See paragraph [0023]. Likewise, it would have been obvious to add an organic amine to the

composition of Omatsu et al. as the results of doing so would have been apparent to one skilled in the art.

11. Claims 18, 19, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al. as applied to claims 9 and 21 above, and further in view of Lippold et al. (US 6,410,338).

With respect to claims 18, 19, and 24, Omatsu et al. is silent with respect to a component which changes color by reacting with hydrogen peroxide. Lippold et al. teaches an indicator for plasma sterilization wherein the indicator includes a salt of aurintricarboxylic acid (col.4, lines 46-48) and which changes color by reacting with hydrogen peroxide. As Omatsu et al. discloses that additional dyes may be used with the anthraquinone in the indicating composition, it would have been obvious to add the indicator of Lippold et al. to Omatsu et al. in order to provide a chemical indicator with redundancy.

As to claims 25 and 26, Omatsu et al. teaches that the layers may be applied so as to be overlapping or mutually exclusive. See paragraphs [0037]-[0045]. One of ordinary skill in the art would have been apprised of suitable printing patterns to optimize use of the indicator.

12. Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al. in view of Nagata et al. (US 6,267,242).

Omatsu et al. teaches use of the indicator composition within a sterilizer along with a load to be sterilized (paragraph [0048]). Omatsu et al. does not disclose placing the indicator on an inner surface of a pouch. Nagata et al. discloses a non-woven

polyethylene pouch having a transparent window wherein a chemical indicator is placed on an inner surface of the pouch such that the indicator can be viewed through the window. See col.4, lines 7-52. As gas-permeable bags are well-known in the art of sterilization as a means of containing a load to be sterilized, it would have been obvious to use the indicator of Omatsu et al. within a gas-permeable bag, as disclosed by Nagata et al..

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/  
Primary Examiner, Art Unit 1797

elm  
1 March 2009